REMARKS/ARGUMENTS

I. Status of Claims and Formal Matters

Claims 1-2, 5-6, 8-15, 18, 25, 28-30, 33 and 36-37 are pending in this application. Claims 3-4, 7, 16-17, 19-24, 26-27, 31-32, 34-35 and 38 were previously canceled. Claims 28-30 and 36-37 have been withdrawn. Claim 2 is canceled with this response, without prejudice to pursuing the subject matter of this claim in one or more continuing application(s). Claim 1 is proposed to be amended. Claim 39 is newly added. Upon entry of the proposed amendments, claims 1, 5-6, 8-15, 18, 25, 28-30, 33 and 36-37 and 39 are pending with claims 1, 5-6, 8-15, 18, 25, 33 and 39 under active consideration. Applicant respectfully requests entry of the proposed amendments and remarks into the file history the present application.

Claim 1 is amended to replace the term "Parkinsonism Plus Syndrome" with the term "Multiple System Atrophy (MSA)."

No new matter is added by the proposed amendments. Paragraph numbers are cited herein with reference to the published application.

II. Patentability Arguments

A. Claim Rejections

1) The Rejections Under 35 U.S.C. 112, First Paragraph (Enablement) Should Be Withdrawn

Claims 1, 2, 6, 8, 10-15, 18, 25 and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner acknowledges that the specification enables a method for the amelioration of the symptoms of Multiple Symptom Atrophy (MSA) comprising administering to a person suffering from MSA a substance consisting of (a) human growth hormone (hGH), (b) a variant of (a) that has at least 70% sequence identity thereto and that has agonistic activity on the hGH receptor, (c) a salt of (a) or (b), wherein administration of said substance ameliorates the symptoms of MSA. Applicants thank the Examiner for acknowledging that the subject matter of claim 1(a)-(c) is enabled. However, the Examiner alleges that the specification does not enable certain aspects of the presently claimed methods.

First, the Examiner alleges that the present specification does not reasonably enable the claims as broadly recited, namely "Parkinsonism Plus Syndrome(s) and those syndromes recited in claim 2." Applicants, solely in the interest of expediting prosecution of the present application and without acknowledging agreement with the Examiner on this issue, propose to amend claim 1 to replace the term "Parkinsonism Plus Syndrome" with "Multiple System Atrophy," subject matter which the Examiner has acknowledged is enabled, at least with respect to claim 1(a)-(c). Moreover, Applicants cancel claim 2 with this response. Accordingly, this aspect of the Examiner's rejection is rendered moot.

Second, the Examiner alleges that the present specification does not reasonably enable the claims with respect to administration of hGHRH. Applicants respectfully traverse this rejection based on the following arguments.

The basis for this aspect of the Examiner's rejection appears to reside in the statement that "[n]either the art, nor the specification, provide guidance as to…whether treatment with hGHRH would be effective." OA at page 8. As an initial matter, Applicants respectfully point out that when an examiner concludes that an application is describing an invention that is non-

useful, inoperative, or contradicts known scientific principles, whether under 35 U.S.C. §§ 112 or 101, the ***burden is on the examiner*** (not on the Applicant) to provide a reasonable basis to support this conclusion. MPEP 2164.07l.B. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. *Id.*

Moreover, it is well settled that a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As is discussed in detail below, Applicants respectfully submit that the Examiner has not provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility and has thus not established a *prima facie* case of lack of utility/operability under 35 U.S.C. § 112, first paragraph

In the present case, the mechanism by which hGHRH exerts its biological effect is well established in the art. Specifically, it is known that GHRH stimulates production of endogenous growth hormone (GH) by binding to the GHRH receptor located in cells of the anterior pituitary. Thus, the present specification teaches:

> It is known that human growth hormone releasing hormone (hGHRH) stimulates the release of hGH. Thus, the biological activity of hGH can be indirectly obtained by administering GHRH or a functional derivative, salt, variant, analog or fragment thereof which retains the biological activity of GHRH, i.e., the ability to stimulate the release of growth hormone. Published application, paragraph [0122].

The present specification teaches that hGH has beneficial effects on patients with MSA; accordingly, one of ordinary skill in the art would reasonably expect administration of hGHRH, which stimulates endogenous production of hGH, to have similar beneficial effects on MSA

patients. As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. MPEP § 2107.03 I. Applicants respectfully submit that the present disclosure combined with knowledge in the art provides a reasonable correlation between the biological activity of hGHRH (i.e., stimulating production of endogenous hGH) and amelioration of symptoms MSA symptoms. Thus, the present specification as filed, combined with knowledge in the art, fully enables one of ordinary skill in the art to practice the invention as presently claimed without recourse to undue experimentation. The Examiner has not pointed to any evidence in the record from which one of ordinary skill in the art would reasonably doubt the asserted utility of what is claimed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC 112, first paragraph.

CONCLUSION.

Applicants respectfully submit that the instant application is in good and proper order for allowance and early notification to this effect is solicited. The Examiner is hereby respectfully invited to contact the undersigned attorney at the telephone number listed below with any questions, comments, or suggestions relating to this application that may advance this application to allowance.

Respectfully submitted,
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